



## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2012-0044]

Cooperative Research and Development Agreement (CRADA) Opportunity with the Department of Homeland Security for the Efficacy Testing of Vaporous Hydrogen Peroxide (VHP) and Chlorine Dioxide (ClO<sub>2</sub>) against Foot and Mouth Disease Virus (FMDV) and African Swine Fever Virus (ASFV) **AGENCY:** Science and Technology Directorate, Plum Island Animal Disease Center, Department of Homeland Security.

**ACTION:** Notice of intent.

**SUMMARY:** The Department of Homeland Security Science and Technology Directorate (DHS S&T), through its Plum Island Animal Disease Center (PIADC), is seeking collaborators to aid DHS S&T in conducting validation testing on the ability of VHP and ClO<sub>2</sub> to achieve sufficient biological load reduction against live FMDV and ASFV. PIADC operates a Biosafety Level 3 (BSL-3) facility working primarily with high consequence foreign animal diseases. The nature of this work makes it paramount to ensure the effective and thorough decontamination of all material exiting the bio containment area within the facility. Rising health concerns and process efficiency/turn-around time with the use of formaldehyde gas (the current fumigation method used against FMDV and ASFV) are key driving factors in validating an alternative fumigation method. The fumigation method(s) will ultimately be used to decontaminate sensitive equipment and electronics, other material within the bio containment area, sealed portions of the facility, biological safety cabinets and perform in-place decontamination of heating, ventilation, and cooling (HVAC) HEPA filtration systems. The role of the

collaborator(s) in this CRADA will be to provide PIADC with the materials, equipment, and technological expertise to support accurate and reliable efficacy testing using VHP and ClO<sub>2</sub>. DHS S&T is seeking CRADA collaborators that own the technological components for, have the technological expertise in, and have proven track records of success in the fields of VHP and ClO<sub>2</sub> decontamination validation studies. The proposed term of the CRADA can be up to eighteen (18) months.

**DATES:** Submit comments on or before September 14, 2012.

**ADDRESSES:** Mail comments and requests to participate to Doug Ports, (PO Box 848, Greenport, NY, 11944). Submit electronic comments and other data to [Douglas.Ports@hq.dhs.gov](mailto:Douglas.Ports@hq.dhs.gov).

**FOR FURTHER INFORMATION CONTACT:**

Information on DHS CRADAs: Marlene Owens, (202) 254-6671.

Information on proposed technical effort: Doug Ports, (631) 323-3210.

**SUPPLEMENTAL INFORMATION:**

Efficacy Testing Plan

The target agents (FMDV and ASFV) and test microorganisms (*Bacillus subtilis*, Vaccinia Virus, *Geobacillus stearothermophilus*, and potentially other commercially available spore strips) will be used to test the efficacy of VHP and ClO<sub>2</sub> on various surfaces including balsa wood, stainless steel, glass, and paper. Phase I of the testing is set to take place at a federal laboratory facility against the test microorganisms, requiring successful results prior to moving on to Phase II. Phase II testing will take place at PIADC (*Plum Island, NY*) against both the test microorganisms and target agents. Phase I and Phase II efficacy testing will not require the VHP or ClO<sub>2</sub> generators to enter the

bio containment area; however, components or probes that do enter the bio containment area will need to be decontaminated using a validated method prior to removal. Testing and decontamination validation will take place using pre-approved methods agreed upon between federal and non-federal personnel. Mutual benefits to both federal and non-federal collaborators include the opportunity to support the Homeland Security Enterprise in protecting the United States from internal and external foreign animal disease threats and response capabilities. Specifically, DHS S&T is interested in validated alternatives to formaldehyde fumigation with respect to outbreak control, infection control, and decontamination for FMDV and AFSV releases. The collaborators will also have the opportunity to test their decontamination methods directly against live FMDV and ASFV at the only laboratory in the United States, and one of few in the world, that works with live FMDV. Efficacy testing data and results may be published in scientific journals by or under the guidance of federal personnel.

#### Period of Performance

Once CRADA collaborators have been selected, finalized Phase I testing is expected to take approximately 3 months. Contingent on Phase I testing results, Phase II testing is expected to take an additional 6 months and data consolidation, analysis, and results finalization is expected to take another 3 months following.

#### Selection Criteria

The Plum Island Animal Disease Center (PIADC) reserves the right to select CRADA collaborators for all, some, or none of the proposals in response to this notice. PIADC will provide no funding for reimbursement of proposal development costs. Proposals (or

any other material) submitted in response to this notice will not be returned. Proposals submitted are expected to be unclassified.

PIADC will select proposals at its sole discretion on the basis of:

- i. How well the proposal communicates the collaborators' understanding of and ability to meet the CRADAs goals and proposed timeline
- ii. How well the proposal addresses the following criteria:
  - a. Capability of the collaborator to provide equipment and materials for proposed Phase I and Phase II efficacy testing.
  - b. Capability of the collaborator to provide on-site and remote technological expertise, within a reasonable time period and for a reasonable duration, for Phase I and Phase II efficacy testing.

Participation in this CRADA does not imply the future purchase of any materials, equipment or services from the collaborating entities; however, non-Federal CRADA participants will not be excluded from any future PIADC procurements based solely on their participation in this CRADA.

Authority: CRADAs are authorized by the Federal Technology Transfer Act of 1986, as amended and codified by 15 U.S.C. 3710a. DHS, as an executive agency under 5 U.S.C. 105, is a Federal agency for the purposes of 15 U.S.C. 3710a and may enter into a CRADA. DHS delegated the authority to conduct CRADAs to the Science and Technology Directorate and its laboratories.

Dated: August 7, 2012

James Johnson,  
Director, Office of National Laboratories.

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